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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,087	08/28/2001	Casey C. Case	8325-0002.21	7166

23419 7590 08/12/2003

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EXAMINER

BRUSCA, JOHN S

ART UNIT PAPER NUMBER

1631

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/942,087

**Applicant(s)**

CASE ET AL.

**Examiner**

John S. Brusca

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2104.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

**DETAILED ACTION**

***Information Disclosure Statement***

1. An Information Disclosure Statement was filed 03 March 2003 but the paper did not contain a listing of the cited references. As such, the paper has not been considered. A second Information Disclosure Statement filed 21 April 2003 has been considered and a signed Form PTO 1449 is attached to this Office action.

***Oath/Declaration***

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either on an application data sheet or supplemental oath or declaration.

It was not executed in accordance with either 37 CFR 1.66 or 1.68.

The signature associated with Alan Wolffe is not identified as that of the legal representative of the deceased inventor. See MPEP 409.01(a).

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 1-24, and 31-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of delivery of zinc finger proteins to cells by introduction of an expression vector, does not reasonably provide enablement for methods of delivery of zinc finger proteins to cells by introduction of exogenous zinc finger proteins to cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation." These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to practice the claimed invention one of skill in the art must regulate endogenous gene expression by delivery of a zinc finger protein to a cell. For the reasons discussed below, there would be an unpredictable amount of experimentation required to practice the claimed invention.

b) The specification does not give specific guidance to deliver zinc finger proteins to cells and cause modulation of expression of an endogenous gene.

c) The specification does not provide working examples of delivery of zinc finger proteins to cells to cause modulation of expression of an endogenous gene.

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d) The nature of the invention, regulation of gene expression by zinc finger proteins, is complex.

e) A search of the prior art does not show regulation of gene expression by delivery of zinc finger proteins to cells by any direct method. Barbas et al. U.S. Patent No. 6,242,568 reviews modulation of expression of genes by zinc finger proteins. Barbas et al. shows manipulation of expression of genes by use of expression vectors encoding modified zinc finger proteins.

f) The skill of those in the art of molecular biology is high.

g) The prior art does not address the predictability of the full scope of the claimed invention.

h) The claims are broad in that they read on (and in claims 136 and 179 specifically claim) embodiments that are not supported by the instant specification or the prior art.

In order to practice the claimed invention, the skilled practitioner would first turn to the teachings of the instant specification to practice embodiments of the claimed invention in which zinc finger proteins are delivered as protein to cells. However, the instant specification does not provide specific guidance or working examples of such embodiments. As such, the skilled practitioner would turn to the prior art for such guidance, however the prior art also does not provide such guidance. Finally, said practitioner would turn to trial and error experimentation to practice the full scope of the claimed invention without guidance from the specification or the prior art. Such represents undue experimentation.

### ***Double Patenting***

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5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would be obvious over, the reference claim(s). see, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

6. Claims 1-8, 10-14, and 25-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12, 18-22, 25-28, 30-41,

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47, 49-51, 54-57, 59-70, 74-78, and 81-84 of U.S. Patent No. 6,534, 261. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of U.S. Patent No. 6,534,261 anticipate the instant claims.

7. Claims 1-8, 10, 11, 14, and 25-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 31, 34-43, 50-54, and 57-60 and 62 of copending Application No. 09/478681. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of copending Application No. 09/478681 anticipate the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1, 2-8, 10-12, 14, 24, 31, 32, and 34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 118-129, 136-139, 141-152, 159-161, 163-170, 172-174, 179-183 of copending Application No. 09/706243. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of copending Application No. 09/706243 anticipate the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1-8, 10-12, 14, and 24-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12, 18-23, 26-29, 31-42, 48-53, 56-59, 61-72, 76-81, and 84-87 of copending Application No. 09/897844.

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Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of copending Application No. 09/897844 anticipate the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1, 12, and 14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 89, 90, and 92 of copending Application No. 10/222614. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of copending Application No. 10/222614 anticipate the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 703 308-4231. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703 308-4025. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872-9306 for regular communications and 703 872-9306 for After Final communications.

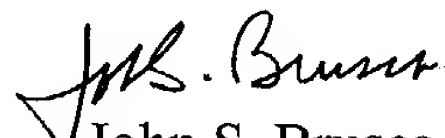


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

  
John S. Brusca  
Primary Examiner  
Art Unit 1631

jsb  
August 7, 2003